

# The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

Division of Health Professions Licensure

Board of Registration in Pharmacy 239 Causeway Street, Suite 200, 2<sup>nd</sup> Floor Boston, MA 02114

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TO: Pharmacist Licensure Applicants

FROM: The Massachusetts Board of Registration in Pharmacy

RE: Multistate Pharmacy Jurisprudence Examination (MPJE)

The Board of Registration in Pharmacy (Board) advises all applicants for licensure as a pharmacist in the Commonwealth of Massachusetts by examination, score transfer, reciprocity or reinstatement to review the reference sources listed below to prepare for the Multistate Pharmacy Jurisprudence Examination (MPJE). This reference document with related web site links may be accessed on the Board's web site (Rules & Regulations icon) at <a href="http://www.mass.gov/dpl/boards/ph/index.htm">http://www.mass.gov/dpl/boards/ph/index.htm</a>.

### THE MULTISTATE PHARMACY JURISPRUDENCE EXAMINATION (MPJE)

The MPJE is a two-hour, computer-adaptive examination developed by the National Association of Boards of Pharmacy (NABP) for use by state boards of pharmacy. The MPJE is based in a nationally uniform content blueprint with questions that are tailored to assess the pharmacy jurisprudence requirements of individual states.

Utilizing the MPJE enables the boards of pharmacy to fulfill one aspect of their mission to safeguard the public health and welfare by allowing candidates to demonstrate their ability to meet the responsibilities of pharmacy practice.

The MPJE consists of 90 multiple-choice questions, 30 of which are designated as pre-test questions that do not affect the candidate's score. The examination content blueprint, which is the percentage of questions asked in each of the MPJE competency areas, is uniform for all candidates. For additional information regarding the MPJE Competency Statements (blueprint), consult the NAPLEX/MPJE Registration Bulletin available on-line at <a href="https://www.nabp.net">www.nabp.net</a>.

The individual questions within each content area will differ from candidate to candidate, depending upon their ability level as estimated by the computer's technology. Therefore, candidate scores are not based solely on the number of correct answers, but on an estimate of the candidate's ability level based on the difficulty of the questions and the number of questions answered correctly.

The MPJE is administered Monday through Friday, excluding holidays, via Pearson Vue Testing Network (888 709 1139), (<a href="https://www.pearsonvue.com/nabp">www.pearsonvue.com/nabp</a>).

## 1. Board of Registration in Pharmacy Regulations 247 CMR Sections 2.00 - 15.00

You are strongly advised to obtain a copy of the Board's Regulations 247 Code of Massachusetts Regulations (CMR) Sections 2.00- 15.00 to prepare for the MPJE. Please verify that you have the current version of the regulations.

#### 247 CMR: BOARD OF REGISTRATION IN PHARMACY

- 2.00 Definitions
- 3.00 Personal Registration Requirements
- 4.00 Personal Registration Renewal; Continuing Education Requirements
- 5.00 Orally and Electronically Transmitted Prescriptions; Electronic Data Transmission System
- 6.00 Registration, Management and Operation of a Pharmacy or Pharmacy Department
- 7.00 Wholesale Distribution of Prescription Drugs
- 8.00 Pharmacy Interns and Technicians
- 9.00 Code of Professional Conduct; Professional Standards for Registered Pharmacists, Pharmacies and Pharmacy Departments
- 10.00 Disciplinary Proceedings
- 11.00 Registration under the Controlled Substances Act (M.G.L.c.94C)
- 12.00 Restricted Pharmacy
- 13.00 Registration Requirements and Minimal Professional Standards for Nuclear Pharmacies
- 14.00 Petition for Waiver
- 15.00 Continuous Quality Improvement Programs

An unofficial copy of the Board's regulations may be accessed on the Board's web site at <a href="http://www.mass.gov/dpl/boards/ph/index.htm">http://www.mass.gov/dpl/boards/ph/index.htm</a>.

# 2. <u>Department of Public Health Regulations 105 CMR Sections 720.00 - 722.00 and Miscellaneous Provisions</u>

Questions on the MPJE on these regulations include, but are not limited to, the Department of Public Health's Regulations pertaining to:

- (a) The Massachusetts Formulary Law; Interchange; and
- (b) Hospital Pharmacies, Interchange, Prescription Formats, Security Standards for Prescriptions and Labeling.

An unofficial copy of the Department of Public Health regulations may be accessed on the Department's web site at <a href="http://www.mass.gov/dph/dcp/dcp.htm">http://www.mass.gov/dph/dcp/dcp.htm</a>.

Official copies of 247 CMR and 105 CMR 720.00 - 722.00 may also be obtained for a fee by requesting the "Pharmacy Package" from:

Secretary of the Commonwealth State Bookstore State House, Room 116 Boston, MA 02133

Telephone: (617) 727-2834

Fax: (617) 973-4858

Email: bookstore@sec.state.ma.us

**Note**: The Executive Office of Administration and Finance regulations 801 CMR Sections 1.00 - 3.00 included in this package are **not** included in the MPJE.

#### 3. Massachusetts General Laws (M.G.L.) Chapters 13, 112 and 94C

Massachusetts General Laws (M.G.L.) may be viewed at the State House Library, any public library or at a library at the schools/college of pharmacy in Massachusetts, or through the website. The General Laws are also viewable on the Internet at <a href="http://www.state.ma.us/legis/laws/mgl/index.htm">http://www.state.ma.us/legis/laws/mgl/index.htm</a> (Insert title and section – for example, Chapter 94C, section 33(b))

#### M.G.L. c. 13, §§ 22 - 25

- 22 Board; Membership; Qualifications; Appointment; Term
- 23 Meetings; officers; secretary's bond
- 24 Salaries and expenses
- 25 Agents; expenses; duties

#### M.G.L. c. 112, §§ 24 - 42A

- 24A Biennial Expiration of Registration: Renewal of Certificates; Striking from Register and Reinstatement
- 24B Standards for School and Colleges of Pharmacy and Courses in Pharmacy
- 25 Records; Annual reports
- 26 Display of Certificate
- 27 Complaint; notice; hearing
- 28 Decision of Board of Registration in Pharmacy; effect
- 29 Suspension
- 30 Unlawful dispensing of controlled substances; penalties...
- 31 Repealed
- 32 Investigation of Complaints
- 33 Access to documents
- 34 Certificate of conviction of pharmacist
- 35 Repealed
- Continuance of business of deceased or incapacitated registered pharmacists 36(a) Licensing of sale, distribution and delivery of drugs or medicines 36(b) Licenses; fees; renewals
  - 36(c) Use of words: wholesale druggist"; inspection and investigation...
  - 36(d) Penalties
- 37 Drug business; definition
- 38 Transaction of retail drug business; registration; permit; display of permit
- Registration; permits; fees; rendering of final decision
  - 39(a) Restricted pharmacies; registration
  - 39(b) Nuclear pharmacies
- 40 Suspension or revocation of registration and permit; notice; hearing
- 41 Penalty
  - 41(a) Patent and proprietary medicines; non-controlled substances; exemption...
- 42 Authorization of expenditures
  - 42(a) Rules and regulations; suspension or revocation of license or permit...

#### M.G.L. c. 94C, §§ 1 - 37 (Massachusetts Controlled Substances Act)

- 1 Definitions
- 2 Establishments of Schedules or other controlled substances
- 3 Required Findings for placement of Controlled Substances in Schedules
- 4 Exceptions from Schedules
- 5 Dispensing controlled substances excepted under sec. 4
- 6 Rules and Regulations
- 7 Registration of persons who manufacture, distribute, dispense or possess controlled substances
- 8 Research project and studies
- 9 Authorized Possession, Administration and Dispensation of Controlled Substances; Records; Inspection
- 10 Separate Registration
- 11 Inspection of establishments or registrants or applicants
- 12 Issuance of registration to manufacturer or distribute controlled substances
- 13 Revocation and Suspension of Registration; Grounds; Embargo
- 14 Suspension or Refusal to Renew upon Finding of Imminent Danger to Public Health or Safety
- 15 Record-keeping and Inventory Requirements
- 16 Distribution between registrants; order form
- 17 Necessity of Prescription for Dispensing of Controlled Substances
- 18 Prescriptions; Who May Issue
- 19 Authorized Purposes for Which Prescriptions May Be Issued
- 20 Pharmacist to Reduce Oral Prescriptions to Writing 20(a): Radiopharmaceutical drugs
- 21 Filling of Prescriptions; Required Information on Label
  - 21(a): Prescriptions, Prospective Drug Review and Counseling by the Pharmacist
- 22 Practitioner Prescribing or Dispensing Controlled Substances; Information Required
- Written prescriptions; Requirements and Restrictions
- 24 Dispensing Controlled Substances to Research Subject or Patient; Harmful Quantities from More than One Source; Notification of Practitioners
- 25 Restrictions
- 26 Distribution in course of business in violation of sec. 16
- 27 Possession, Delivery, or Sale of Hypodermic Syringe, Needle or Similar Instrument Regulated; Prescriptions, Records, Licenses; Pilot Needle Exchange Program
- 28 Jurisdiction of Superior Court
- 29 Education Programs for prevention of abuse of controlled substances
- 30 Administrative Inspections of controlled premises
- 31 Classes of controlled substances, establishments of criminal penalties for violations
- 32 Class A controlled substances; unlawful manufacture, distribution, dispensing or possession
  - (32a) Class B controlled substances...
  - (32b) Class C controlled substances...
  - (32c) Class D controlled substances...
  - (32d) Class E controlled substances...
  - (32e) Trafficking in marihuana, cocaine, heroin, morphine, opium, etc.
  - (32f) Unlawful manufacture, distribution, dispensing or possession...
  - (32g) Counterfeit substances; unlawful creation, distribution, dispensing or possession...
  - (32h) Prosecutions
  - (32I) Drug paraphernalia
  - (32j) Controlled substances violations...
  - (32k) Inducing or abetting minor to distribute or sell controlled substances
- 33 Unlawful use of registration numbers in manufacture or distribution...

- 34 Unlawful possession of particular controlled substances including heroin...
- 35 Unlawful presence at a place where heroin is kept or being in company of...
- 36 Protective Custody of children found present where controlled substances are...
- 37 Theft of controlled substances from persons authorized to dispense or possess

Candidates should also review applicable federal laws and regulations: Title 21 of Code of Federal Regulations (CFR) Part 1300 - 1308. Contact the U.S. Government Printing Office (Tel. (202) 512-1800) for copies or you may access this information on the U.S. DEA web site at: http://www.deadiversion.usdoj.gov/.

#### OTHER STUDY MATERIAL RECOMMENDATIONS

Drug Enforcement Administration (DEA) - see above referenced web site. Pharmacist's Manual:

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/index.htm

Poison Prevent Packaging Act 16 CFR 1700 (refer to summary below) - may be accessed at:

http://www.cpsc.gov/businfo/regsumpppa.pdf (summary)

http://www.cpsc.gov/cpscpub/pubs/384.pdf

Prescription Drug Marketing Act - may be accessed at:

http://www.fda.gov/cber/rules/pdmapol050300.pdf

FDA statutes governing Recalls, Misbranding, Adulterated Drugs - may be accessed at:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=7.3&SearchTerm=recalls

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse\_usc&docid=Cite:+21USC351

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse\_usc&docid=Cite:+21USC352

The Federal Food, Drug and Cosmetic Act (FDCA) - may be accessed at:

http://www.access.gpo.gov/uscode/title21/chapter9\_.html

Massachusetts Board of Registration in Medicine Regulations 243 CMR Section 2.07 (19)(20)(21) and "Prescribing Practices: Policies & Guidelines" - may be accessed at:

http://www.massmedboard.org/regs/

http://www.massmedboard.org/regs/pdf/prescribe2.pdf

FDA regulations governing labeling directions - may be accessed at:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=201.57

FDA regulations governing Patient Package Inserts - may be accessed at:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=310.515

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=310.501